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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,437	12/18/2001	Galla Chandra Rao	FF MP 01	6369
40541	7590	11/18/2004	EXAMINER	
IMMUNICON CORPORATION 3401 MASONS MILL ROAD SUITE 100 HUNTINGDON VALLEY, PA 19006			YU, MELANIE J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/017,437

Applicant(s)

RAO ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/1/2003.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of group I, claims 1-11 and 15-17 in the reply filed on October 7, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 12-14 have been withdrawn from consideration as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-11 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, it is unclear whether the magnetic particle is actually bound to the non-magnetic particle, the limitation of being capable of binding does not mean the magnetic particle is actually bound to the non-magnetic particle. It is unclear how many free binding sites are encompassed by variable amounts of free binding sites.

With respect to claim 6, it is unclear if the magnetic particles are actually directly or indirectly bound to the at least three additional entities. It is also unclear if the three additional entities must be capable of binding to the magnetic particle simultaneously and if the at least three additional entities must be different.

Regarding claim 7, it is unclear if the detectable labels are linked to the first binding partner of claim 1, or the detectable labels are linked to a different first binding partner. It is unclear if the additional entities listed are targets for binding or the additional entities are attached to the magnetic particle for the binding other targets.

With respect to claims 15-17, the recited term “size” is vague and indefinite because it is unclear to what dimension the size is referring.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kausch et al. (US 5,665,582).

Kausch et al. teach a composition comprising non-magnetic microparticles operably linked with a first binding partner (col. 11, line 65 – col. 12, line 1) capable of binding to a complementary second binding partner, said binding partner being operably linked to magnetic particles (col. 18, lines 54-57) smaller than the average size of the non-magnetic particles (col. 12, lines 1-6), wherein the non-magnetic microparticles are either unlabeled (col. 13, line 62 – col. 14, line 10; col. 18, lines 57-61) or detectably labeled (col. 15, lines 4-10; col. 18, lines 57-61). Kausch et al. teach the first binding partner being biotin (between the microbead and the cell, col. 14, lines 6-10; between the magnetic particle and the cell, col. 18, lines 54-57) and the

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complementary binding partner being an avidin species (avidin coated magnetic particles, col. 18, lines 54-57).

Regarding claims 6-11, Kausch et al. teach free binding sites on the layer of magnetic particles that are capable of directly or indirectly binding at least three additional entities (col. 21, lines 12-25). The additional entities are selected from the group consisting of: one or more target specific third binding partners, being an oligonucleotide probe complementary to a target oligonucleotide sequence or an antibody, operably linked to said first binding partner (col. 17, lines 44-47; col. 23, lines 41-42; col. 34, lines 20-35); a fluorescent compound linked to the first binding partner (col. 6, lines 16-36; col. 8, lines 9-11; col. 18, lines 54-64; col. 20, lines 29-32); a biotin species with affinity for blocking residual binding sites on the second binding partner located on the magnetic microparticles (col. 24, lines 3-13); and a detectably labeled target specific fourth binding partner capable of recognizing epitopes on target entities different from those recognized by the third binding partner (a nucleic acid probe is specific to proteins; col. 18, lines 7-10).

4. Claims 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Liberti et al. (US 6,013,532).

Liberti et al. teach a composition comprising magnetic particles bound to particles having a detectable fluorescent label (col. 12, lines 35-58), said magnetic particles having an average diameter of 0.2  $\mu\text{m}$  or less (col. 5, line 65 – col. 6, line 7), which is less than the average diameter of the particles having a detectable fluorescent label with a size of 10  $\mu\text{m}$  (col. 7, lines 58-62), which falls within the recited range of an average size from about 1 to about 20  $\mu\text{m}$ .

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***Conclusion***

No claims are allowed.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wang et al. (US 5,091,206) teach a layer of small magnetic particles coated on a larger non-magnetic particle, but fail to teach binding between biotin and avidin species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1641



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11/12/04